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510(k) SUMMARY
OF
SAFETY and EFFECTIVENESS

A. General Information

1.	*Submitter's Name*	Cimex BioTech, L.C.
2.	*Address:*	72385 Industry Park Covington, LA 70435
3.	*Telephone:*	985-871-0802
4.	*Contact Person*	Michael Haas, M.D.
5.	*Date Prepared:*	July 10, 2001
6:	*Registration Number*	2320472

B. Device

1.	*Name:*	CryoPen (Model CP -010 and Accessories)
2.	*Trade name:*	CryoPen and Accessories
3.	*Common Name:*	Cryosurgical Unit and Accessories
4.	*Classification Name:*	Unit, Cryosurgical, Accessories
5.	*Product Code:*	GEH
6.	*Class:*	II
7.	*Regulation Number:*	878.4350

Description of the Device

The CryoPen system provides a means of freezing tissue without the use of cryogenic liquids or gases. The system consists of three hand-held freezing modules, a refrigeration unit, and disposable tips. When used properly, the system will deliver effective temperature for tissue ablation.

The refrigeration component is the largest unit, and is used to lower the temperature of the CryoPen units to temperature of -100 C. It operates on 115 VAC obtained from conventional convenience outlets. The supporting housed in the refrigerator cabinet include a DC power source to indicate the temperature of the CryoPen units during cool down, and all other necessary control and electrical safety features.

There are currently three different sizes of the hand-held modules: a 0.4 inch diameter unit, a 0.25 inch diameter unit, and a 0.19 inch diameter unit.

C. Intended Use Statement

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The CryoPen is intended to be used as a Cryosurgical unit for ablative type surgical technique.

The CryoPen is indicated for use on multiple organ systems, including a wide range of disease (i.e. viral, benign, pre-malignant and malignant tissue).

D. Components

CONTENTS:	**PART NUMBER:**
(1) CryoPen Cooling System Assembly	CP-001100-01
(2) CryoPen Module Assembly (0.4 in)	CP-004300-01
(3) CryoPen Module Assembly (0.25 in)	CP-004200-01
(4) CryoPen Module Assembly (0.19 in)	CP-004100-01
(5) Disposable tips (0.4 in)	CP-004302-01
(6) Disposable tips (0.25 in)	CP-004202-01
(7) Disposable tips (0.19)	CP-004102-01
(8) CryoPen Cool-Down Fixture Plug	CP-006001-01

E. Substantial Equivalence

The CryoPen System is Substantially Equivalent to the Wallach LL100 Predicate Device, approved on February 04, 1981, (reference K803311). The CryoPen and the Wallach LL100 destroy tissue using cryogenic temperatures. The contacting metal incorporated in the cryotips used with the CryoPen™, are made of pure silver, which differs from the predicate contact material of stainless steel. A predicate device using silver is K981299 Silverlon™ Contact Wound Dressing. Appropriate biocompatibility testing was performed on this predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Michael J. Haas, M.D.
Vice President of Research and Development
Cimex Bio-Tech
72385 Industry Park
Covington, LA 70435

Re: K012214
Trade/Device Name: CryoPen and Accessories
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: Class II
Product Code: GEH
Dated: February 22, 2002
Received: February 28, 2002

Dear Dr. Haas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost
for Celia Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K012214

Device Name: CryoPen System

Indications For Use:

- Intended Use: Cryosurgical unit used for ablative type surgical technique
- Indications for use: Multiple organ systems, wide range of disease, viral, premalignant and malignant tissue.

PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription USE __V__ **or OVER - THE - COUNTER - USE**_____
(Optional Form 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K012214